FORM PTO-1083

BOX:

ASSISTANT COMMISSIONER FOR PATENTS

Washington, DC 20231

In re application of:

OSHLACK, et al.

Serial No.: Filed: 09/781,076 February 8, 2001

For:

CONTROLLED-RELEASE COMPOSITIONS CONTAININ

JAN 2 9 2003

AGONIST AND ANTAGONIST

Sir:

Transmitted herewith is an Amendment in the above-identified application.

[] Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.

A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.

[X] No fee for additional claims is required.

[] A filing fee for additional claims calculated as shown below, is required:

			(Col. 1)	(Col. 2)	SMALL ENTITY	LARGE ENTITY
		FOR:	REMAINING	HIGHEST	RATE FEE	OR RATE FEE
DEOT	An		AFTER	PREVIOUSLY	PRESENT	
DE2	AVA	MARIEC	AMENDMENT	PAID FOR	EXTRA	
		TOTAL LATENS	UP Minus	20 ≈	x \$ 9 \$	x \$ 18 \$ .00
		INDEP. CLAIMS	Minus	3 =	x \$ 39 \$	x \$ 78 \$ .00
		[ ] FIRST PRES	SENTATION OF	MULTIPLE D	EP. CLAIN130 \$	+ \$260  \$ .00
					TOTAL: \$ OR	TOTAL: \$ .00

\* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.

\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Also transmitted herewith are:

[X] Petition for three month extension under 37 C.F.R. 1.136 (in duplicate)

[X] Other: Response to Office Action

[X] Check(s) in the amounts of \$930.00 attached to cover:

[ ] Filing fee for additional claims under 37 C.F.R. 1.16

[X] Petition fee for three month extension under 37 C.F.R. 1.136

[ ] Other: Surcharge for late filing of the executed Declaration and fee

[X] The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

[X] Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.

[X] Any patent application processing fees under 37 C.F.R. 1.17.

Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR

1.136.

Robert J. Paradiso, Esq., Reg. No. 41,240 DAVIDSON, DAVIDSON & KAPPEL, LLC

ara

Docket No.: 200.1134

Date: \_January 22, 2003

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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on <u>January 22, 2003</u>. DAVIDSON, DAVIDSON & KAPPEL, LLC

DAVIDSON, DAVIDSON & RAPPEL, LLC



## UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: J. Russel Art Unit: 1653

Re:

Application of:

OSHLACK, et al.

Serial No.:

09/781,076

Filed:

February 8, 2001

For:

CONTROLLED-RELEASE COMPOSITIONS

**CONTAINING OPIOID AGONIST AND** 

**ANTAGONIST** 

## AMENDMENT UNDER 35 CFR § 1.111

**Assistant Commissioner for Patents** Washington, D.C. 20231

January 22, 2003

Sir:

In response to the Office Action mailed July 22, 2002 please amend the application as follows:

## IN THE SPECIFICATION

Please replace the second paragraph on page 3 with the following new paragraph:

In certain preferred embodiments, the present invention comprises a controlled release dosage form that delivers an opioid agonist and an opioid antagonist over an extended period of time. In these oral embodiments, the dosage form includes an amount of an opioid agonist, preferably a bimodally-acting opioid agonist, and an amount of an opioid antagonist, and upon administration the dosage form delivers an analgesic or sub-analgesic amount of the opioid agonist over the dosing interval, along with an amount of the opioid antagonist effective to

